

AMENDMENT

Serial No. 09/523,237
Atty. Docket No. GP068-03.CN1

488. (New) The kit of claim 485 further comprising a solid support for directly or indirectly immobilizing said capture probe, wherein said capture probe includes a seventh base sequence which does not hybridize to said target nucleic acid under nucleic acid assay conditions.

489. (New) The kit of claim 474, wherein at least one of said first and second amplification oligonucleotides is unlabeled.

490. (New) The kit of claim 474 further comprising written instructions for performing a polymerase chain reaction method of amplification.

491. (New) The kit of claim 474 further comprising written instructions for performing a transcription-based method of amplification.

* * * * *

Remarks

Claims 442-491 are presently pending in the subject application.

Reconsideration and allowance in view of the above amendments and the following remarks are respectfully requested.

Claims 422-441 are canceled herein without prejudice to the prosecution of the subject matter of these claims in this or a future continuing application.

Claims 442-491 are newly added herein. These new claims are being presented to emphasize that at least one of the oligonucleotides included in the claimed kits is an amplification oligonucleotide containing at least one ribonucleotide modified to include a 2'-O-methyl substitution to the ribofuranosyl moiety. New claims 442-491 are fully supported by the originally presented claims and/or by the specification. In particular, Applicants wish to point out that the unlabeled amplification oligonucleotides recited in some of the new claims are supported by the specification

which teaches, in a preferred embodiment, a transcription-based amplification method in which a target sequence and the resulting amplicon is detected with a labeled probe, clearly conveying to those skilled in the art that labeled amplification oligonucleotides are not included in this preferred embodiment. *See, e.g.*, specification at page 30, lines 6-21; *see also See Ex parte Parks*, 30 USPQ2d 1234, 1236 (BPAI 1994) (“it is sufficient if the originally-filed disclosure would have conveyed to one having ordinary skill in the art that an [applicant] had possession of the *concept* of what is claimed”) (citation omitted) (emphasis added). Moreover, numerous U.S. patents are incorporated by reference into Applicants’ disclosure which teach amplification methods using unlabeled amplification oligonucleotides and labeled probes for detecting amplification products. *See, e.g.*, specification at page 23, lines 14-21. *See* MPEP § 2163.07(b) at 2100-128 (7th ed., Rev. 1, Feb. 2000). Accordingly, Applicants submit that use of the term “unlabeled” in connection with amplification oligonucleotides recited in the claims does not constitute new matter.

Double Patenting Rejection

Claims 422-441 stand provisionally rejected by the Examiner under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 444-465 of co-pending application Serial No. 09/565,427. As this is a provisional rejection, and the claims of the instant application are otherwise believed to be in condition for allowance, withdrawal of this rejection is respectfully requested. *See* MPEP § 804 at 800-15 (7th ed., Rev. 1, Feb. 2000) (“If the ‘provisional’ double patenting rejection in one application is the only rejection remaining in that application, the examiner should then withdraw that rejection and permit the application to issue as a patent, . . .”). And, contrary to the Examiner’s representation, Applicants did not acknowledge the propriety of this double patenting rejection in their previous response, but rather stated that they would address this provisional rejection once claims were indicated to be in condition for allowance.

Rejection Under 35 U.S.C. § 102(e)

Claims 422, 427-431, 433-441 stand rejected by the Examiner under 35 U.S.C. § 102(e) as being anticipated by Van Gemen *et al.* (U.S. Patent No. 5,679,553). Applicants submit that this rejection is rendered moot by Applicants' cancellation of the previously pending claims and the introduction of new claims 442-491. These new claims include three independent claims which recite the following: (i) a 2'-O-methyl modified amplification oligonucleotide which includes a promoter sequence (claim 442); (ii) a 2'-O-methyl modified, unlabeled oligonucleotide in combination with one or more reagents for performing an amplification reaction (claim 458); and (iii) a pair of amplification oligonucleotides, at least one of which includes a 2'-O-methyl modification, where, under amplification conditions, one of the amplification oligonucleotides hybridizes to a region 5' to the target sequence and the other amplification oligonucleotide hybridizes to a region of a nucleic acid which is complementary to a region 3' to the target sequence (claim 474). Applicants submit that Van Gemen fails to disclose or suggest the use of 2'-O-methyl modified amplification oligonucleotides for amplifying a target nucleic acid sequence. Accordingly, withdrawal of this rejection is respectfully requested in view of the newly presented claims.

Rejections Under 35 U.S.C. § 103(a)

Claims 423-426 stand rejected by the Examiner under 35 U.S.C. § 103(a) as being unpatentable over Van Gemen *et al.* (U.S. Patent No. 5,679,553). Applicants submit that this rejection is rendered moot by Applicants' cancellation of the previously pending claims, and that this rejection is not applicable to the presently pending claims for the reasons discussed above. Accordingly, withdrawal of this rejection is respectfully requested.

Claim 432 stands rejected by the Examiner under 35 U.S.C. § 103(a) as being unpatentable over Van Gemen *et al.* (U.S. Patent No. 5,679,553) in view of Cruickshank (U.S. Patent No. 5,091,519). Applicants submit that this rejection is rendered moot by Applicants' cancellation of the previously pending claims, and that this rejection is not applicable to the presently

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pending claims for the reasons discussed above. Moreover, Applicants further submit that Cruishank fails to provide any teaching that would overcome the deficiencies Applicants identified above in the Van Gemen reference. Accordingly, withdrawal of this rejection is respectfully requested.

Marked-Up Copy of Amendments

In accordance with 37 C.F.R. § 1.121, Applicants are attaching hereto marked-up versions of the amendments made to the title and specification herein.

Conclusion

Applicants submit that the subject application is in condition for allowance and Notice to that effect is respectfully requested.

No fee is believed due in connection with this Amendment. If Applicants are mistaken, please charge the amount due to Deposit Account 07-0835.

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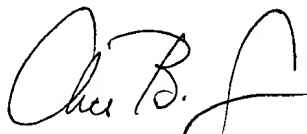
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I hereby certify that this correspondence (along with any referred to as being attached or enclosed) is being deposited on the date indicated below with the U.S. Postal Service as first class mail addressed to Box RCE, Commissioner for Patents, Washington, D.C. 20231.

Respectfully submitted,

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Marked-Up Copy of Amendments

IN THE CLAIMS:

Previously pending claims 422-441 have been canceled and claims 442-491 have been newly added. Therefore, no mark-up of the claim amendments is needed.

IN THE TITLE:

The title of the invention has been amended as follows:

KITS FOR AMPLIFYING TARGET NUCLEIC ACIDS USING MODIFIED
[PRIMERS] OLIGONUCLEOTIDES.

IN THE SPECIFICATION:

The first sentence of the specification has been amended as follows:

This is a continuation of [Application] U.S. application Serial No.
08/893,300, filed July 15, 1997, now U.S. Patent No. 6,130,038, the contents of which are
hereby incorporated by reference herein, which claims the benefit of U.S. Provisional
Application No. 60/021,818, filed July 16, 1996